

# **EXHIBIT 195**



**GIANT EAGLE  
FRAUD, WASTE &  
ABUSE COMPLIANCE  
MANUAL**

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## I. INTRODUCTION

Because compliance with applicable laws and regulations is a top priority for Giant Eagle Inc., we are implementing a Compliance Program, which sets forth the standards we believe will ensure compliance with applicable legal requirements relating to its pharmacy operation.

This Compliance Program Manual (the “Manual”) provides a description of these standards and Giant Eagle Inc.’s framework for implementing the Compliance Program. The success of the company’s compliance efforts depends on each employee’s dedication to working with us to implement the Compliance Program. The Compliance Program describes the company’s expectations for employees,<sup>1/</sup> and others associated with Giant Eagle Inc. and provides guidance on dealing with compliance issues that may arise in the daily course of business. In particular, all employees are responsible for acting consistently with the company’s Compliance Policies and Procedures, including the Code of Conduct.<sup>2/</sup>

## II. WRITTEN POLICIES AND PROCEDURES

Giant Eagle Inc. has established written policies, procedures, and standards that demonstrate our commitment to complying with all applicable federal and state statutory, regulatory, and other requirements relating to its pharmacy operation. These policies and procedures are a critical component of our efforts to detect, prevent, and control fraud, waste, and abuse. Giant Eagle Inc. will update all Compliance Policies and Procedures as necessary to remain current with legal and other current developments. All policies will be available for review on GE Central, which is the Giant Eagle information sharing portal.

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<sup>1/</sup> References to “employees” in this Manual include those individuals who contract with Giant Eagle Inc. to perform functions integral to Giant Eagle Inc. that are customarily performed by employees. For example, a pharmacist who independently contracts with Giant Eagle Inc. to provide professional services on a part-time basis would be an “employee” for limited purposes of this Manual.

<sup>2/</sup> Nothing in this Manual is intended to limit Giant Eagle Inc.’s right to terminate any employment or contractual relationship. Except as may otherwise be provided in any employee’s or independent contractor’s written contract, Giant Eagle Inc. has the right to terminate any employee or independent contractor at any time, with or without cause. The Manual is not a contract of employment and may be modified by Giant Eagle Inc. in its sole discretion.

## **Code of Conduct**

All employees must act in an ethical manner and adhere to applicable legal requirements in the course of performing their duties on behalf of Giant Eagle Inc. The Code of Conduct, which is attached at Appendix 1, articulates the company's commitment to comply with all statutory, regulatory, and other requirements and its expectations for employees in this regard. It also describes the ramifications of any failure to comply with the Code of Conduct.

## **Policies and Procedures**

In addition to the Code of Conduct, Giant Eagle Inc. has developed more detailed Compliance Policies and Procedures to guide conduct and to assist employees in addressing specific areas of possible fraud, waste, and abuse. These Compliance Policies and Procedures may be found at Appendix 5 to this Manual.

## **III. PHARMACY COMPLIANCE OFFICER AND COMMITTEE**

### **A. Pharmacy Compliance Officer**

The Company has appointed a Pharmacy Compliance Officer its V.P. of Pharmacy, who is in charge of all compliance activities. The Pharmacy Compliance Officer is responsible for developing, operating, and monitoring the Compliance Program and reports directly to the Corporate Compliance Officer, and the President of Supermarkets of Giant Eagle Inc. The Pharmacy Compliance Officer maintains appropriate oversight of any duties that are delegated.

The duties for which the Pharmacy Compliance Officer is responsible include but are not limited to:

- communicating regularly with and reporting to the Corporate Compliance Officer, and the President of Supermarkets on the status of Compliance Program implementation and other compliance-related issues;
- assisting the Corporate Compliance Officer, and the President of Supermarkets and the Pharmacy Compliance Committee in establishing methods to reduce the company's vulnerability to fraud, waste, and abuse;
- creating, coordinating, and participating in educational training programs to ensure all affected employees, and others who work on behalf of Giant Eagle Inc. are knowledgeable of the company's Compliance Program, Code of Conduct, Compliance Policies and Procedures, and applicable statutory, regulatory, and other requirements;

- monitoring legal and regulatory developments as well as generally accepted professional standards governing the pharmacy industry and updating the Manual as appropriate;
- developing and maintaining retribution-free methods and programs for reporting suspected misconduct;
- working with the human resources department to ensure that Giant Eagle Inc. conducts appropriate background checks of affected employees, and others who work on behalf of Giant Eagle Inc., vendors, and other contractors;
- ensuring that allegations of misconduct are investigated, that follow-up activity is properly documented, and that corrective action is instituted as necessary;
- developing and implementing tools for monitoring and auditing;
- seeking guidance from legal counsel on reporting self-discovered violations of federal health care program requirements or other compliance issues;
- maintaining documentation for each report of potential fraud, waste, or abuse received through any of the reporting methods;
- providing information to and responding to questions from employees, and others about compliance-related issues; and
- performing any other responsibilities as directed by the Corporate Compliance Officer, and the President of Supermarkets.

## **B. Pharmacy Compliance Committee**

The Company has also established a Pharmacy Compliance Committee. Its purpose is to advise the Pharmacy Compliance Officer and to assist in implementation and oversight of the company's Compliance Program.

To ensure various perspectives are considered, the Pharmacy Compliance Committee consists of individuals from various parts of Giant Eagle Inc. Members include at least one pharmacist, as well as representatives of senior management from billing/finance, human resources, legal, sales, and marketing.

The Pharmacy Compliance Committee's duties include but are not limited to:

- meeting as necessary, but not less than bi-annually;
- supporting the Pharmacy Compliance Officer's needs for sufficient staff and resources to carry out his or her duties;

- analyzing the company's regulatory environment, applicable legal requirements, and specific risk areas to ensure Compliance Policies and Procedures are appropriate and up-to-date;
- developing strategies to promote compliance and the detection of any potential violations;
- recommending and monitoring a system of internal controls to carry out the company's compliance standards as part of its daily operations;
- working with the appropriate individuals and departments to ensure adherence to the Compliance Program and to ensure that training and education are appropriately completed;
- ensuring Giant Eagle Inc. has a system for employees, and others to ask compliance questions and to report potential instances of fraud, waste, or abuse confidentially and without fear of retaliation;
- assisting with the creation and implementation of monitoring and auditing plans, reviewing and addressing monitoring and auditing results, and ensuring that corrective action plans are implemented and monitored; and
- providing reports on the status of compliance with recommendations to senior management.

#### **IV. TRAINING AND EDUCATION**

Giant Eagle Inc. has implemented a training program to help employees identify, prevent, and report noncompliance. Participation is required. Failure to comply with the company's training requirements may result in disciplinary action, including possible termination. The Pharmacy Compliance Officer verifies that all required employees attend compliance training and maintains training records.

All pharmacy employees, compliance committee members, officers and senior management must participate in compliance training upon initial hire or engagement and at least annually thereafter and attendance at each session must be documented. The Pharmacy Compliance Officer will reevaluate the content of compliance training at least annually. Specific course content may include but is not limited to:

- a description of the Compliance Program, including a review of the Compliance Policies and Procedures, the Code of Conduct, and the company's commitment to business ethics;
- an overview of the compliance communication process, including instruction on how to ask compliance questions, request compliance clarification, or report potential non-compliance;

- a review of the disciplinary guidelines for non-compliant or fraudulent behavior; or
- a review of the False Claims Act and related state and federal fraud and abuse and whistleblower laws; and
- As deemed appropriate by the Pharmacy Compliance Officer and Pharmacy Compliance Committee, special compliance training will be provided those employees whose responsibilities require specific training such as submission and reimbursement of claims.

## **V. EFFECTIVE LINES OF COMMUNICATION**

Employees are expected to report suspected violations of the company's Compliance Policies and Procedures, including the Code of Conduct and applicable laws and regulations. An employee should make such reports to his or her supervisor or to the Pharmacy Compliance Officer. Such reports should contain enough information to allow investigation into the concerns raised.

### **A. Compliance Hotline and Other Forms of Communication**

Employees and others may communicate any ethical or compliance-related questions or concerns in person or by telephone, email, or other written communication. Giant Eagle Inc. has a toll-free hotline for employees or others that is accessible twenty-four hours a day, seven days a week. Callers have the opportunity to leave an anonymous voice mail message. The toll-free number is 1-800-498-8889. Callers are encouraged to leave as much detail as possible in the message, as well as a name and/or contact number in order to enable a thorough investigation.

Giant Eagle Inc. notifies customers of the opportunity to submit complaints. The toll-free customer service phone number is (800) 553-2324. Giant Eagle Inc. tracks complaints, addresses customer concerns, and records each step of the process.

### **B. Anonymity**

The identity of those reporting potential fraud, waste or abuse is generally protected if the individual wishes to remain anonymous. Giant Eagle Inc. will take reasonable efforts to ensure the confidentiality of reports made to the hotline including, but not limited to, ensuring limited access to written and electronic records and ensuring that hotline calls are received in a manner that protects the confidentiality and privacy of the individual reporting and the information being reported.

### **C. Non-Retaliation**

Giant Eagle Inc. will not engage in nor tolerate retaliation against individuals who report suspected wrongdoing. No reprisal, reprimand, or disciplinary action will be permitted or will be taken against anyone who discloses a compliance-related concern in good faith

through the proper reporting procedures. This policy does not insulate the reporter from disciplinary action if it turns out that he or she is involved in any wrongdoing.

#### **D. Documentation of Reports**

The Pharmacy Compliance Officer documents and tracks all reported concerns and issues as well as the status of related investigations and corrective actions. Compliance-related questions and compliance personnel answers also are documented, dated, and shared with others as appropriate.

### **VI. ENFORCEMENT OF STANDARDS**

Employees are expected to comply with the Code of Conduct and to adhere to applicable legal requirements during the course of performing their duties on behalf of Giant Eagle Inc. Failure to do so may result in disciplinary action.

#### **A. Immediate Termination**

Certain offenses may justify the immediate termination of Giant Eagle Inc.'s relationship with an employee. Such wrongdoing includes but is not limited to:

- violation of federal or state fraud and abuse laws;
- failure to report conduct that the individual knows is illegal or that a reasonable person would have known is illegal;
- intentional provision of materially false information to Giant Eagle Inc., a customer, or a payer; and
- knowing provision of false or misleading information to the Pharmacy Compliance Officer or the Pharmacy Compliance Committee.

#### **B. Incremental Discipline**

Conduct that would otherwise justify termination may result in less severe disciplinary action if the violator self-reported or if the individual cooperated fully during the investigation. However, anyone who self-reports is not immune from termination or other disciplinary action.

Less severe disciplinary action may include, but is not limited to, coordination with human resources and a conference with the employee's supervisor, a written warning, or suspension without pay. As with all disciplinary measures, incremental discipline must be applied consistently to all offenders.

### **C. Accountability of Senior Management, Supervisors, and Other High-level Employees**

As with all employees, senior management, supervisors, and other high-level employees must report known violations of the Compliance Program or risk disciplinary action. In addition, such individuals also are responsible for the actions of subordinates if they either facilitate or fail to appropriately forward reports made to them as a result of their own negligence, carelessness, or inattention.

## **VII. PROMPT RESPONSES TO DETECTED OFFENSES AND CORRECTIVE ACTION**

Through the Compliance Program, Giant Eagle Inc. ensures prompt responses to and appropriate corrective actions for detected offenses. Responses to detected offenses vary according to the circumstances and may include immediate referral to criminal or civil law enforcement, a corrective action plan, and/or return of overpayments.

### **A. Internal Investigations**

The Pharmacy Compliance Officer will conduct a timely and reasonable investigation of all credible reports of suspected noncompliance. A reasonable inquiry includes a preliminary investigation by the Pharmacy Compliance Officer or other compliance personnel. Giant Eagle Inc's protocol for internal investigations may be found at Appendix 4 to this Manual.

If an internal investigation results in the discovery of misconduct that may violate applicable laws or regulations, the Pharmacy Compliance Officer will consult with legal counsel before deciding how to proceed.

### **B. Government Investigations**

Giant Eagle Inc's policy is to be forthright and cooperative when dealing with government investigations, inquiries, or information requests. If an employee of Giant Eagle Inc. is contacted by a government agent or employee, he or she should refer to Appendix 2, which describes the company's protocol for responding to government investigations.

### **C. Corrective Actions**

Corrective actions aim to remedy the underlying problem that resulted in misconduct. It may include disciplinary action, prompt identification and refund of overpayments, or other actions. Each corrective action plan will be tailored to the particular misconduct identified. Documentation will include: specifying all elements of the plan, the ramifications for non-compliance and defining ongoing monitoring to ensure that the plan is carried out.

## **VIII. MONITORING AND AUDITING**

Internal monitoring and auditing both are important aspects of Giant Eagle Inc's Compliance Program. Such activities can detect and prevent compliance problems through verification of compliance with contractual agreements, applicable state and federal requirements, and the Compliance Policies and Procedures. The Pharmacy Compliance Officer, in consultation with the Pharmacy Compliance Committee, develops monitoring and auditing work plans, as described in Appendix 3 of this Manual. Further, Giant Eagle Inc. may be the subject of audits by the Centers for Medicare and Medicaid Services, other government agencies, or entities with which it contracts, such as sponsors of Medicare Part D prescription drug plans. The protocol for responding to audits conducted by outside entities is set forth in Appendix 3 to this Manual.

The purpose of monitoring activities is to ensure corrective actions are carried out and to confirm ongoing compliance even when no specific problems are identified. The system of ongoing monitoring assesses performance in, at minimum, identified risk areas.

Auditing is a more formal review of compliance with a particular set of internal or external standards used as base measures. Internal standards may include the Manual's Compliance Policies and Procedures. External standards may include laws and regulations. The Pharmacy Compliance Officer and the Pharmacy Compliance Committee, along with legal counsel, will arrange for audits of certain risk areas, such as billing and pricing, dispensing, Medicare Part D promotional activities as needed.

## **APPENDIX 1**

### **CODE OF CONDUCT**

#### **I. INTRODUCTION**

All employees must act in an ethical manner and adhere to applicable legal requirements in the course of performing their duties on behalf of Giant Eagle, Inc. This Code of Conduct, which is part of Giant Eagle Inc's Compliance Program, is intended to be a clear and concise summary of fundamental ethical standards with which all employees must comply when conducting business on the company's behalf. Giant Eagle Inc's Compliance Policies and Procedures provide more detailed rules designed to ensure that Giant Eagle Inc. and those associated with it act legally and ethically at all times.

Giant Eagle Inc. expects all employees to read and adhere to the standards described in the Code of Conduct as a condition of employment. Any employee who violates the Code of Conduct will be subject to disciplinary action, up to and including termination.

Giant Eagle Inc. has endorsed the Code of Conduct and, with the Pharmacy Compliance Officer's assistance, will monitor its implementation on an ongoing basis.

#### **II. STANDARDS OF CONDUCT**

##### **A. Comply with Laws and Regulations**

All employees must comply with Giant Eagle Inc's Compliance Program, including the Compliance Policies and Procedures and with applicable laws and regulations in letter and in spirit. If employees have questions about the laws and regulations that apply to Giant Eagle Inc. or about the company's policies and procedures for complying with them, they are expected to seek guidance from supervisors, the Pharmacy Compliance Officer, or members of the Pharmacy Compliance Committee.

##### **B. Act Ethically and Avoid Conflicts of Interest**

Giant Eagle Inc. expects all employees to conduct business on its behalf in an honest, fair, and ethical manner and in the company's best interests, without regard to personal considerations. Employees must refrain from participating in any activities or business endeavors that could pose a conflict with their responsibilities to Giant Eagle Inc. and to its customers.

Every new employee who will in any way interact with pharmacy third party information must reveal any convictions related to health care or any debarment, exclusion, sanction, or other adverse action taken against him or her by any federal or state agency. Giant Eagle Inc. will revalidate this information periodically and require all applicable employees to give Giant Eagle Inc. notice if any such action is initiated.

**C. Protect the Privacy of Customer Information and the Confidentiality of Giant Eagle Inc's Records**

All employees must respect the confidential nature of protected health and any proprietary information received in the course of their work on behalf of Giant Eagle Inc. In particular, employees must comply with state and federal laws and regulations, including the Health Insurance Portability and Accountability Act (known as "HIPAA"), governing the privacy and security of protected health information.

**D. Prepare and Submit Accurate and Complete Claims for Payment**

Preparing and submitting accurate and complete reimbursement claims is among Giant Eagle Inc's top priorities. Giant Eagle Inc. expects employees to adhere to the laws, regulations, and internal policies and procedures governing the billing and claims submission process. Employees must not present or cause to be presented any false or fraudulent claims for payment.

**E. Properly Dispense Prescriptions**

Giant Eagle Inc. promotes full compliance with applicable dispensing requirements. All employees involved in the dispensing process must carry out their duties in accordance with legal and ethical standards and maintain a comprehensive working knowledge of all laws, regulations, and internal policies and procedures applicable to dispensing.

**F. Participate in Compliance and Other Training Sessions**

All pharmacy and other personnel involved in dispensing of prescriptions or submissions of claims for reimbursement under federal health care programs, including, but not limited to Medicare Part D must participate in compliance training and other professional skills development activities necessary to carry out their respective duties effectively and, if applicable, to maintain required professional licensure. Affected employees must sign a certification documenting participation in compliance training sessions.

**G. Report Compliance Violations**

Employees must report suspected violations of Giant Eagle Inc's Compliance Policies and Procedures or applicable laws and regulations. Giant Eagle Inc. encourages employees to come forward even if they are unsure of whether any misconduct has occurred. Giant Eagle Inc. will not engage in or tolerate retaliation against any employee who in good faith reports suspected wrongdoing and will allow anonymity to the extent appropriate.

**H. Cooperate with Internal and External Investigations**

The Pharmacy Compliance Officer will conduct a timely and reasonable investigation of all credible reports of suspected noncompliance, and Giant Eagle Inc. expects everyone

affiliated with it to cooperate fully with these investigations. Outside entities, such as government agencies and private third party payers, also may conduct investigations related to suspected noncompliance, and Giant Eagle Inc. encourages everyone to be forthright and cooperative.

### **III. CONSEQUENCES OF NONCOMPLIANCE**

Failure to meet Giant Eagle Inc's expectations for compliance with any law, regulation, or internal policy may result in the imposition of discipline, up to and including termination. The promotion of and adherence to the Compliance Program is an important element in the evaluation of all employees, especially senior management, supervisors, and other high-level employees responsible for facilitating the compliance of employees under their supervision.

## APPENDIX 2

### PROTOCOL FOR RESPONDING TO GOVERNMENT REQUESTS AND REVIEWS

#### PURPOSE:

Because health care is a heavily regulated activity, Giant Eagle Inc. and in particular its pharmacy operations are likely to be subject to frequent and routine government requests and reviews. This policy provides basic guidelines to assist Giant Eagle Inc. employees in dealing with government requests and reviews. If you are unsure how to respond to a particular government request or review, you should contact your regional manager, the Pharmacy Compliance Officer, and/or the General Counsel immediately.

#### POLICY:

Giant Eagle Inc.'s policy is to cooperate fully with all appropriate government requests and reviews. This policy seeks to assure that Giant Eagle Inc.'s responses to government requests and reviews are complete, accurate, and timely. It is also important for Giant Eagle Inc. to properly coordinate its responses and to ensure that the rights of those involved are protected.

#### PROCEDURE:

##### IN GENERAL

In addition to the formal legal documents discussed below (*i.e.*, subpoenas, summonses, and legal complaints), Giant Eagle Inc. and its pharmacy operations may receive requests from government health care programs (such as Medicare Part D and Mediciad), other third-party payors, and various contractors seeking backup documentation or copies of prescriptions as well as more formal audit requests. It is important that a supervisor be made aware of **non-routine** requests for documentation and **all** formal audit requests.

Giant Eagle Inc. and its pharmacy operations also may be subject to periodic visits from various government officials and their contractors. These visits may range from a routine police inquiry about a prescription for a controlled substance, to an annual Board of Pharmacy site inspection, to a rare instance in which law enforcement agents attempt to execute a search warrant (search warrants are discussed separately below). Depending on the nature and circumstances of such visits, it is critical that a supervisor, regional manager, Pharmacy Compliance Officer, and/or the General Counsel be notified immediately.

**Keep in mind that if you are unsure how to respond to a particular government request or review, you should err on the side of caution and immediately contact your regional manager, the Pharmacy Compliance Officer, and/or the General Counsel for guidance.**

## **SUBPOENAS, SUMMONSES, AND LEGAL COMPLAINTS**

### **1. Handling Subpoenas, Summons, and Legal Complaints**

If you are served with a subpoena (other than routine subpoenas for medical or personnel records, which are processed, by Giant Eagle Inc.'s Legal Department) summons, or legal complaint involving Giant Eagle Inc., notify the General Counsel immediately. You should follow the General Counsel's instructions carefully and promptly. If you are unable to reach the General Counsel, send a facsimile of the document to his or her attention immediately, noting your name, the date you received the document, and when and where you can be reached.

- (a) DO NOT turn over documents called for in a subpoena (until instructed to do so by Giant Eagle Inc. management);
- (b) DO NOT discuss the case with the individual who served you with the subpoena; and
- (c) DO NOT discuss the subpoena with anyone other than legal counsel.

If your help or testimony is needed, legal counsel for Giant Eagle Inc. will contact you directly with instructions on how to assist in the effort.

### **2. Procedures for Assuring Compliance with all Legal Complaints, Subpoenas, Summons, and Court Orders**

The General Counsel will maintain a record of every legal complaint, subpoena, summons, and court order served on Giant Eagle Inc. or which otherwise requires the assistance or cooperation of Giant Eagle Inc. The General Counsel will be responsible for employing outside legal counsel, where required.

The General Counsel will have primary oversight duties to assure complete and prompt compliance with the court document in question or filing of necessary pleadings to answer, suppress, quash, modify, or otherwise protect the response.

## **SEARCH WARRANTS**

A search warrant is a court order obtained by prosecutors that gives law enforcement agents the right to enter the premises specifically identified in the warrant for the purpose of seizing any documents and objects specified in the warrant. If law enforcement agents attempts to execute a search warrant at any Giant Eagle Inc. location, the following steps should be taken:

1. Do nothing to interfere with the agents.
2. Request a copy of the search warrant and the business card (or name) of the agent in charge.
3. Be sure the highest-ranking Giant Eagle Inc. employee on premises is informed of the situation immediately.
4. Call the General Counsel. Follow his or her instructions carefully.

5. Attempt to assure that:

- (a) only those items referred to in the search warrant are taken;
- (b) Giant Eagle Inc. documents are not photocopied by the agents on the premises (unless approved by the General Counsel); and
- (c) a correct and complete inventory of all items taken is given to you before the agents leave the premises.

Finally, just because the agents have the right to be on the premises to execute a search warrant does not mean Giant Eagle Inc. employees must submit to interviews. You are *not* required to explain Giant Eagle Inc. operations, bookkeeping, or records, or to explain what any document means. You should cooperate in *locating* those items specified in the search warrant and no more. If an agent makes requests or demands of you inconsistent with these instructions, you should seek the advice from the General Counsel.

## **APPENDIX 3**

### **MONITORING AND AUDITING**

#### **PURPOSE:**

An internal monitoring and auditing system protects Giant Eagle Inc. and others from fraud, waste, and abuse. In addition, ongoing evaluation of Giant Eagle Inc's compliance with applicable statutes and regulations will promote the provision of high quality services.

#### **POLICY:**

Giant Eagle Inc. endeavors to monitor, audit, and evaluate its compliance with internal and external rules. The nature of reviews as well as the extent and frequency of monitoring and auditing varies according to a number of factors, including new regulatory requirements, changes in business practices, and other considerations.

#### **PROCEDURE:**

The Pharmacy Compliance Officer leads the development of auditing and monitoring workplans to address Giant Eagle Inc's risk areas and oversees workplan implementation. Workplans should be structured to assess the effectiveness of the Compliance Program and should indicate areas targeted for revision or improvement. To the extent that monitoring or auditing activity reveals potential misconduct, Giant Eagle Inc. will commence an internal investigation pursuant to Appendix 4 to determine whether misconduct has occurred and take disciplinary and corrective action as appropriate.

Workplans should include a schedule of all monitoring or auditing activities, as appropriate, for the year. In addition, each workplan should detail the responsible staff member, start and completion dates of the activity, whether it will be announced or unannounced, whether it will be on-site or desk, and the date on which the Pharmacy Compliance Officer should receive the results. The General Counsel should have a key role in workplan development.

#### **I. MONITORING**

A thorough and ongoing evaluation of various aspects of the Compliance Program is critical to its success. Upon initial implementation of a Compliance Program, the Pharmacy Compliance Officer will oversee development of a workplan that will include the elements noted above. In addition, the workplan will identify the components and activities needed to perform assessments, such as the types of monitoring and the targets of the monitoring activity.

The workplan may identify a variety of assessment techniques such as:

- use of statistical methods for random selection of pharmacies and other areas of review, for determining the appropriate sample size, and for extrapolation of findings using statistically valid and generally accepted standards;
- interviews of management regarding perceived levels of compliance within their areas of responsibility;
- development of questionnaires to poll employees regarding compliance matters such as the effectiveness of training;
- review of training content and related attendance certificates, the reporting mechanisms, the Code of Conduct, investigation files, and sanction screenings;
- performance of audits pursuant to a Workplan developed to target a specific area to review (see below);
- exit interviews of departing employees; and
- follow-up review of areas previously found non-compliant to determine if the corrective actions taken have fully addressed the problem.]

As part of its assessment activities, Giant Eagle Inc. may generate and review reports for its own purposes and also may need to relay the same information to Medicare Part D sponsors. The following are examples of such assessment tools identified by the Centers for Medicare and Medicaid Services (“CMS”) in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse:

- **Payment Reports**, which are used to identify over and under payments, duplicate payments, timely payments, and pricing aberrances, and to help verify correct pricing.
- **Drug Utilization Reports**, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.
- **Prescribing Patterns by Physician Reports**, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.
- **Geographic Zip Reports**, which identify possible “doctor shopping” schemes or “script mills” by comparing the geographic location (zip code) of the

patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

## **II. AUDITING**

At the discretion of the Pharmacy Compliance Officer and Pharmacy Compliance Committee, Giant Eagle Inc. Pharmacies shall be subject to routine and random auditing of its records and documents, including a review of such documentation as prescriptions, invoices, pharmacy licenses, claim transaction records, signature logs, purchase records and pricing records, as appropriate. Additionally, such audits shall verify that each pharmacy is in compliance with the applicable state minimum standards of practice and that each pharmacy posts or distributes to Part D beneficiaries notices instructing the beneficiaries to obtain coverage determinations or requests and exceptions if they disagree with the information provided by a pharmacist.

## **III. ASSESSMENT RESULTS**

Information obtained through monitoring and auditing efforts should be regularly provided to the Pharmacy Compliance Officer and retained pursuant to Giant Eagle Inc's document retention policy. The Pharmacy Compliance Officer should provide updates on the assessment results to the Pharmacy Compliance Committee.

## **IV. RESPONDING TO AUDIT REQUESTS FROM OUTSIDE ENTITIES**

CMS, its designees (such as the Medicare Drug Integrity Contractors), or Medicare Part D plan sponsors may contact Giant Eagle Inc. to request records or access to facilities to conduct on-site audits. An employee who receives such a request should contact his or her supervisor or the Pharmacy Compliance Officer immediately. Giant Eagle Inc. will cooperate with any properly authorized request for records or request for facility access.

## **APPENDIX 4**

### **PROTOCOL FOR INTERNAL INVESTIGATIONS**

The Pharmacy Compliance Officer, with the assistance of Giant Eagle Inc's General Counsel, will adhere to the following protocol when responding to detected offenses.

#### **I. EVALUATION**

The Pharmacy Compliance Officer will assess the validity of all credible reports of suspected wrongdoing and will determine whether a comprehensive investigation is warranted. Such assessments should be initiated immediately, but in no case later than two weeks after receiving the report. All reports will be documented including: a description of the allegation, the date the report was received, initial review results, and the type of activity used to evaluate the allegations.

When it is determined that an allegation does not merit further investigation, this will be recorded together with an analysis of the facts that resulted in the conclusion. The Pharmacy Compliance Officer should submit the log and related documentation to the Pharmacy Compliance Committee for review. All relevant documents, including copies of the corresponding log entry, should be kept in a secure location, in accordance with Giant Eagle Inc's record management policy.

#### **II. INVESTIGATION**

Following an initial evaluation, the Pharmacy Compliance Officer may conclude that allegations require further investigation. The Pharmacy Compliance Committee, or Giant Eagle Inc's legal counsel in consultation with the Pharmacy Compliance Officer, will develop an investigation strategy, which is tailored based on information known about the matter. The investigation will begin promptly thereafter.

The Pharmacy Compliance Officer, a Pharmacy Compliance Committee member, the Pharmacy Compliance Officer's designees, or a team of the aforementioned individuals may conduct the investigation. Each investigation will determine, among other things, the scope of the problem (i.e., whether the incident is isolated or systemic) and the depth of the issue (i.e., whether a single individual or a group is involved). The Pharmacy Compliance Officer and legal counsel, along with any other individuals conducting the investigation, will determine whether the alleged misconduct represents a violation of the Compliance Program or a legal requirement, poses a risk to the public, or jeopardizes Giant Eagle Inc.

#### **III. RESPONSE**

The Pharmacy Compliance Officer should consult with legal counsel when an investigation results in a conclusion that a violation of the Compliance Program has likely occurred. Legal counsel will submit a report of the conclusions and their basis to the Pharmacy Compliance Committee. The Pharmacy Compliance Committee will

determine what corrective actions are appropriate under the circumstances and will initiate the selected course of action in consultation with the Pharmacy Compliance Officer and legal counsel.

The Pharmacy Compliance Officer and legal counsel will immediately report findings to the Pharmacy Compliance Committee when an investigation results in a conclusion that: (1) a violation of state or federal law or regulations has occurred, (2) the wrongdoing poses a risk to the general public, or (3) the wrongdoing jeopardizes Giant Eagle Inc. The Pharmacy Compliance Committee, with the assistance of legal counsel, will decide what corrective and preventative actions should be taken.

Upon completion of an investigation that identifies serious misconduct, the Pharmacy Compliance Officer and the Pharmacy Compliance Committee will re-examine the effectiveness of the Compliance Program. The Pharmacy Compliance Committee will make the modifications necessary to prevent a recurrence.

#### **IV. EMERGENCY MATTERS**

The Pharmacy Compliance Officer may determine that a compliance-related matter is an emergency requiring immediate action or that a certain matter is extremely sensitive or confidential. In such case, the Pharmacy Compliance Officer, within his or her sole discretion, may report the matter immediately to legal counsel, who will then report it to senior management without first consulting with the Pharmacy Compliance Committee. The Pharmacy Compliance Officer must provide to legal counsel written documentation of the reasons for any such direct contact with legal counsel, who will then provide such documentation to senior management. If the Pharmacy Compliance Officer determines, and senior management agrees, that action is warranted without the Pharmacy Compliance Committee's involvement, the Pharmacy Compliance Officer will follow the procedures specified in the Compliance Program for conducting the investigation and reporting on its progress. However, such reports will be made to legal counsel and to senior management rather than to the Pharmacy Compliance Committee. Senior management will have sole discretion to determine whether information regarding the investigation will be disclosed to the Pharmacy Compliance Committee or to any party other than legal counsel.

## **APPENDIX 5A**

### **BILLING AND PRICING**

#### **PURPOSE:**

This policy sets forth the billing and reimbursement policies and procedures with which all employees must comply.

#### **POLICY:**

Accurate pricing, billing, and claims submission is a top priority for Giant Eagle Inc. Giant Eagle Inc. is committed to ensuring that all prescriptions and related services are furnished in accordance with applicable federal and state laws, regulations, and directives and with the requirements of all public and private third party payers.

#### **PROCEDURE:**

##### **I. ACCURATE AND COMPLETE CLAIMS DOCUMENTATION**

Employees must ensure that billing documentation is accurate and complete and that it conforms to the applicable payer's requirements. All requests for reimbursement must contain only true and accurate data.

##### **II. DOCUMENT RETENTION**

Employees are expected to maintain documentation demonstrating that prescriptions were prescribed, dispensed, and received. Payers often take the position that a service was not performed unless the pharmacy has documentation supporting that fact. Consequently, documentation must be obtained and retained for all services furnished by Giant Eagle Inc., in accordance with the company's records management policy and with all applicable legal and contractual requirements.

##### **III. SUSPECTED OR IDENTIFIED BILLING DISCREPANCIES**

Examples of potential billing or reimbursement fraud, waste, and abuse include but are not limited to the following:

- filling a prescription with a cheaper generic drug but billing the payer for the more costly brand name drug;
- billing for non-existent prescriptions;
- billing multiple payers for the same prescription;

- billing a payer more than once for the same prescription;
- failing to return credit balances to payers and/or customers;
- intentionally providing less than the prescribed quantity without telling the customer or arranging to provide the balance of the prescription, and then billing for the full prescription;
- billing for prescriptions that are never picked up and therefore returned to stock;
- splitting prescriptions in order to receive additional dispensing fees; and
- illegally diverting pharmaceuticals.

Any employee who identifies such discrepancies with respect to claims already submitted must report them immediately in accordance with the requirements of Giant Eagle Inc's Compliance Program. Prompt reporting is crucial because these and other billing and reimbursement discrepancies can lead to violations of the federal False Claims Act and other state and federal health care fraud and abuse laws. Employees can learn more about these laws by reading Giant Eagle Inc's policy on Inducements, Kickbacks and False Claims.

#### **IV. PRICING**

Giant Eagle Inc. prices its products fairly, competitively, and in accordance with applicable contract provisions and legal requirements, including laws requiring Giant Eagle Inc. to provide usual and customary prices to state Medicaid programs.

Giant Eagle Inc. offers discounts only for proper business reasons and in accordance with applicable laws and regulations and its third party contracts. Giant Eagle Inc. accepts discounts from suppliers and vendors on items to be furnished to federal health care program beneficiaries only if the arrangement complies with a safe harbor under the federal Anti-kickback Statute. Before discounts can be granted, the responsible party must submit a proposal. Each proposal is evaluated individually. Final proposal adoption must comply with Giant Eagle Inc's pricing approval guidelines.

Giant Eagle Inc. strives to ensure that all communication to outside individuals and entities is truthful, accurate, and complete. The prices advertised or otherwise communicated to customers and others are the prices ultimately charged at the point of sale.

With respect to Medicare Part D, Giant Eagle Inc. negotiates the prices it will charge with each Medicare Part D plan sponsor. As required by federal law, Giant Eagle Inc. offers Part D beneficiaries the price negotiated with his or her plan sponsor. Further, to discharge its public disclosure obligations, Giant Eagle Inc. informs Medicare Part D

enrollees of any differential between the price of the prescribed drug and the price of the lowest priced generic version of that drug available at that pharmacy under the enrollee's plan. This information generally is provided at the time the enrollee purchases the drug.

## **APPENDIX 5B**

### **PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION**

#### **PURPOSE:**

This policy sets forth Giant Eagle Inc's expectations for the privacy and security of protected health information and the company's proprietary information.

#### **POLICY:**

Giant Eagle Inc. expects employees to protect the privacy and security of protected health information and its proprietary information in accordance with applicable state and federal laws and regulations and the company's policies and procedures.

#### **PROCEDURE:**

##### **I. PRIVACY OF PROTECTED HEALTH INFORMATION**

Giant Eagle Inc's Code of Conduct requires every employee to respect the confidential nature of health and personal information and to use or disclose such information as allowed by law. As a general matter, this obligation continues even after employment ends. In particular, Giant Eagle Inc. is committed to maintaining the privacy of protected health information ("PHI") that is provided to Giant Eagle Inc. in accordance with the Health Insurance Portability and Accountability Act ("HIPAA"), a federal law that provides rules for how healthcare professionals must handle and transmit medical information and records.

Giant Eagle Inc. has a planned and systematic process for implementing, reviewing, revising, and assuring compliance with the policies and procedures required by HIPAA. All employees must review and comply with these policies and procedures.

##### **II. SECURITY OF ELECTRONIC PROTECTED HEALTH INFORMATION**

Giant Eagle Inc. also is committed to maintaining the security of electronic PHI in accordance with HIPAA and therefore has implemented appropriate policies and procedures addressing required administrative, physical, and technical safeguards. All employees must review and comply with these policies and procedures.

##### **III. LIMITATION ON DISCLOSURE**

Each employee or contractor with access to PHI information acknowledges that under the HIPAA privacy rules, Giant Eagle Inc. Pharmacy must limit the use and disclosure of protected health information (PHI) of individuals who use our pharmacy and acknowledges the responsibility to protect the privacy of PHI to which they gain access in the performance of their job duties.

## **APPENDIX 5C**

### **DISPENSING**

#### **PURPOSE:**

Various federal and state statutes and regulations govern the dispensing process, and the purpose of this policy is to articulate clear requirements for those involved in the dispensing process.

#### **POLICY:**

Giant Eagle Inc. promotes full compliance with applicable dispensing requirements by mandating that all individuals involved in the dispensing process maintain high ethical standards and a strong knowledge of all laws and regulations applicable to dispensing.

#### **PROCEDURE:**

In accordance with state and federal statutes, regulations, and guidelines, including the requirements of the state and federal health care programs, and in the interest of customer safety and effective control over all prescription drugs bought, stored, or dispensed by Giant Eagle Inc., prescription medication is dispensed only under the following guidelines.

#### **I. REQUIREMENTS FOR DISPENSING**

##### **A. Authorized Person Rules**

Only persons legally authorized to dispense prescription medications may do so.

##### **B. Documentation Rules**

All drugs obtained by prescription should be properly labeled. The label of all dispensed medication must include:

- manufacturer's trade or generic name and manufacturer's name,
- directions for use and any cautionary statements,
- patient name,
- prescriber name,
- date of issue,
- the dispensing pharmacy's name and address,
- prescription number,
- strength of drug prescribed,
- quantity of drug supplied, and
- prescription expiration date.

Additionally, the label of any drug listed as a “controlled substance” in Schedules II, III, or IV of the Federal Controlled Substances Act must contain the following warning: *“CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.”*

Upon dispensing a prescription drug, the following information should be recorded on the backtag or other appropriate form(s):

- date dispensed (month/date/year),
- insurance carrier and insurance type if applicable,
- amount dispensed,
- directions for use,
- initials of the dispensing pharmacist,
- initials of the verifying pharmacist,
- patient name,
- name of prescriber, and
- prescription number.

#### **C. Generic Substitution Rules**

All drugs obtained by prescription will be dispensed in accordance with applicable state statutes and regulations permitting or requiring the employee to substitute a generic version of the prescribed drug if all prescription requirements are met. All employees must comply with any applicable state statutes and regulations requiring customer consent or notification of generic drug substitution.

#### **D. Return of Unused Prescription Drugs**

Giant Eagle Inc. is committed to ensuring the strength, quality, purity, and identity of all products dispensed. A pharmacist or other employee must not return drug products to stock once they have been out the possession of the pharmacy. Specifically, a pharmacist or employee must not dispense drug products returned by one patron to another patron. Where appropriate, billing adjustments will be made with regard to returned prescriptions.

#### **E. Procedures for Returning Drugs to Manufacturers**

When a drug is returned to a wholesaler, manufacturer or Capital Returns because it has expired, been recalled, or otherwise required to be returned, the pharmacist or other employee should record the following information on the appropriate inventory control record:

- date returned,
- name of product returned,
- quantity returned,
- value of the product returned, and
- company to whom drug was returned.

#### **F. Pedigree Compliance Rules**

Giant Eagle Inc. endeavors to maintain the accuracy and safety of prescriptions and to guard against dispensing counterfeit medication. To this end, and in accordance with any applicable statutes and regulations, an employee should when necessary request a drug's pedigree identifying each prior sale, purchase, or trade of a drug, including the dates of those transactions and the names and addresses of all parties to them. This authentication will occur upon receipt of a suspect prescription drug product from the manufacturer or other individual or entity. The employee should notify the Food and Drug Administration ("FDA") and other appropriate agencies of suspected counterfeit drugs.

#### **G. Inventory**

Each pharmacy should keep a perpetual inventory and have the ability, at all times, to report by drug/NDC number, quantity, and cost of goods for inventory sold.

The pharmacist or other employee should perform inventory checks when deemed appropriate by the pharmacist in charge or the Pharmacy Compliance Officer. The responsible employee will record his or her name, the date of inventory and quantity. If possible, the employee will rectify any differences between actual count and number recorded in the pharmacy computer system and will notify the Pharmacy Compliance Officer of any unresolved discrepancies.

#### **H. Prohibitions on Dispensing Procedures to Avoid Fraud, Waste, and Abuse**

To prevent fraud, waste, and abuse, Giant Eagle Inc. prohibits all employees from engaging in any of the following activities:

- dispensing any prescription without proper authorization;
- knowingly creating or dispensing a false prescription;
- concealing or attempting to conceal from Giant Eagle Inc. a dispensing error;
- altering a prescription to increase the quantity prescribed or the number of refills without the prescriber's permission;
- dispensing a prescription drug that was not stored or handled in accordance with manufacturer or FDA requirements;
- dispensing a prescription that is beyond its expiration date or is not refillable according to applicable legal requirements;
- charging a patient or billing a third party payer for the full amount of a prescription but providing less than the prescribed quantity without informing the patient or making arrangements to provide the full balance;
- giving inappropriate pricing discounts; or
- knowingly billing a third party plan for a false or nonexistent prescription or exceeding authorized parameters of a prescription plan.

## **II. Audit Procedures**

Internal audits will be preformed regularly in accordance with Giant Eagle Inc's auditing procedure.

## **APPENDIX 5D**

### **EMPLOYING OR CONTRACTING WITH SANCTIONED OR EXCLUDED INDIVIDUALS OR ENTITIES**

#### **PURPOSE:**

This policy establishes Giant Eagle Inc.'s process for ensuring that it does not employ or contract with individuals or entities that are banned from doing business with the government. By not employing or contracting with such parties, Giant Eagle Inc. protects itself, and those with whom it does business, from fraud, waste, and abuse, and also ensures that Giant Eagle Inc. is eligible for reimbursement from government health care programs.

#### **POLICY:**

Giant Eagle Inc. makes a reasonable and prudent effort to avoid submitting to government entities claims for products or services furnished by any person or entity excluded from doing business with the government.

#### **PROCEDURE:**

Giant Eagle Inc. reasonably inquires into the background of new employees with access to pharmacy or pharmacy billing information. In addition, Giant Eagle Inc. periodically confirms that these individuals and entities have not been convicted of a criminal offense related to healthcare or have not been debarred, excluded, or sanctioned by a federal or state agency.

#### **I. Prospective Employees with access to Pharmacy or Pharmacy Billing information**

Prospective employees with access to pharmacy or pharmacy billing information, must, among other things, reveal to Giant Eagle Inc. any convictions for criminal offenses related to health care or any debarment, exclusion, sanction, or other adverse action taken again the individual or entity by government health care programs or any other federal or state agency. Prospective employees must acknowledge in writing, on the employment application, that all information furnished is subject to verification; that the verification process may continue subsequent to affiliation; and that any misrepresentations, falsifications, or omissions of facts shall be grounds for disciplinary action, up to and including termination.

Termination Provision: "This Contract may be terminated by Giant Eagle Inc. immediately upon notice that [Contractor/Employee] has been excluded from participation in a state or federal health care program or that [Contractor/Employee] has been adjudicated or determined to have committed an action which could subject it to exclusion."]

Before employment or any contractual relationship begins, Giant Eagle Inc's human resources department will determine whether the individual or entity at issue appears on the relevant lists of excluded individuals and entities compiled by the Office of Inspector General ("OIG") and other government agencies. Giant Eagle Inc. will refuse to be associated with any individual or entity that appears on these exclusion lists.

## **II. Existing Employees AND Contractors**

Current employees and contractors are required to notify the Pharmacy Compliance Officer or their supervisor immediately upon receipt of any information indicating that the individual or entity has been charged with a crime relating to healthcare or is facing a proposed debarment, exclusion, or other adverse action. Failure of the employee or contractor to report pending action or related information may lead to immediate termination of the relationship.

If Giant Eagle Inc. learns that criminal charges or a proposed debarment or exclusion is pending against an existing employee or contractor, the individual or entity will be removed from direct responsibility for, or involvement in, the company's activities related to government health care programs. Although Giant Eagle Inc. reviews the relevant lists of excluded individuals and entities prior to its association with an individual or entity, Giant Eagle Inc. also checks those lists at least annually for the names of current employees and contractors.

## **APPENDIX 5E**

### **INDUCEMENTS, KICKBACKS AND FALSE CLAIMS**

#### **PURPOSE:**

This policy outlines Giant Eagle Inc's rules regarding offering, providing, soliciting, or receiving something of value in connection with the referral of federal health care program business to or by Giant Eagle Inc. Also, it outlines the rules relating to false claims.

#### **POLICY:**

Giant Eagle Inc. is committed to compliance with federal laws prohibiting health care fraud and abuse. Generally, the laws described below govern Giant Eagle Inc's relationships with federal health care program customers and referral sources, and these laws are implicated most often in the context of inducements and kickbacks.

#### **APPLICABLE FEDERAL LAWS:**

##### **I. ANTI-KICKBACK STATUTE**

The federal Anti-Kickback Statute prohibits the provision or receipt of any remuneration to induce a referral for, or for ordering, services covered by a federal health care program. "Remuneration" includes anything of value. Soliciting or accepting remuneration is as illegal as offering or paying such remuneration.

Violation of the Anti-Kickback Statute can result in substantial criminal and civil penalties. Such penalties may include imprisonment for up to five years, fines of up to \$25,000, not including fines applicable to corporations as a result of application of the federal corporate sentencing guidelines, and exclusion from the federal health care programs. The Civil Monetary Penalties Law, discussed below, establishes additional penalties for Anti-Kickback Statute violations, including payment of up to three times the amount of remuneration involved and \$50,000 for each item or service at issue. The False Claims Act also has been used to sanction Anti-Kickback Statute violations, and it can result in the imposition of treble damages plus \$5,500 to \$11,000 penalties for each false claim. The Civil Monetary Penalties Law and the False Claims Act are both discussed in more detail below.

##### **II. CIVIL MONETARY PENALTIES LAW**

The Civil Monetary Penalties Law ("CMP Law") allows the Office of Inspector General for the Department of Health and Human Services ("OIG") to impose civil monetary penalties against any person or entity that presents or causes to be presented a claim to a

federal or state agency that the person or entity knows or should know was not provided as claimed or was false and fraudulent. It also prohibits the following conduct:

- offering remuneration to a state or federal health care program beneficiary that the person knows or should know is likely to influence the beneficiary to obtain items or services billed to a state or federal health care program,
- employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal health care program,
- billing for services requested by an unlicensed physician or an excluded provider, and
- billing for medically unnecessary services.

The penalties for violating the CMP Law include fines of up to \$10,000 per item or service; payment of up to three times the amount billed, depending on the nature of the offense; and exclusion. As mentioned above, it also provides for additional penalties for Anti-Kickback Statute violations.

### **III. SAFE HARBORS**

The OIG has promulgated safe harbor regulations specifying types of conduct that will not subject individuals or entities to sanctions under the Anti-Kickback Statute, certain provisions of the CMP Law, and the exclusion authorities. To obtain safe harbor protection, each aspect of the arrangement or conduct at issue must satisfy all the requirements of the applicable safe harbor. Failure to fall within the strict parameters of a safe harbor does not necessarily mean that the specified conduct or business arrangement is illegal. However, if all applicable safe harbor requirements are not met, the OIG will analyze the situation based on its particular facts and circumstances. Giant Eagle Inc. considers and seeks to comply with the safe harbor regulations whenever they are applicable to its activities or business arrangements.

### **IV. FALSE CLAIMS ACT**

The False Claims Act (“FCA”) forbids knowing and willful false statements or representations made in connection with a claim submitted for reimbursement to a federal health care program, including Medicare or Medicaid. The FCA extends to those who have actual knowledge of the falsity of the information as well as those who act in deliberate ignorance or in reckless disregard.

Examples of a false claim include submitting a claim for a service that was not rendered or billing multiple payers for the same service. Penalties include fines from \$5,500 to \$11,000 per false claim, payment of treble damages, and exclusion.

The FCA includes a whistleblower provision, which allows someone with actual knowledge of alleged FCA violations to file suit on the federal government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but, if it declines to do so, the whistleblower still may pursue the suit. A whistleblower who prevails may qualify for 15 to 30 percent of the amount recovered on the government's behalf as well as attorney's fees and costs.

The FCA prohibits employers from retaliating against employees who file or participate in the prosecution of a whistleblower suit. An employee who suffers retaliation may, for example, qualify for back pay or reinstatement.

## V. PHYSICIAN SELF-REFERRAL PROHIBITION (THE "STARK LAW")

The federal Stark Law prohibits a physician from referring patients to an entity for certain designated health services if the physician, or an immediate family member of the physician, has a financial relationship with the entity, **unless the financial relationship falls within certain exceptions**. A financial relationship may consist of an ownership or investment interest or a compensation arrangement. A compensation arrangement involves, with certain exceptions, anything of value given to a physician, whether directly or indirectly, overtly or covertly, in cash or in kind. The designated health services covered by this statute include:

- (a) clinical laboratory services;
- (b) physical therapy services;
- (c) occupational therapy services;
- (d) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
- (e) radiation therapy services and supplies;
- (f) durable medical equipment and supplies;
- (g) parenteral and enteral nutrients, equipment, and supplies;
- (h) prosthetics, orthotics, and prosthetic devices and supplies;
- (i) home health services;
- (j) outpatient prescription drugs; and
- (k) inpatient and outpatient hospital services

A "referral" for any of these services includes a request for any of these services or for a consultation regarding these services, or the request or establishment of a plan of care

that includes the provision of any of these services. Further, the “Start Law” is not intent-based”; whether the parties intend to provide an inducement for referrals is not relevant.

Violations of the statute are punishable with civil money penalties of up to \$15,000 per claim plus two times the reimbursement claimed and exclusion from federally-funded health care programs.

The “Stark Law” provides various exceptions, each of which has various requirements that must be met.

- *Exceptions Relating to Both Ownership/Investment and Compensation*

The following services, which relate to ownership/investment and compensation, are excepted from the self-referral prohibition:

- a) services furnished personally by, or under the personal supervision of, another physician in the same group practice;
- b) in-office ancillary services;
- c) services furnished to prepaid health plan enrollees by certain organizations;
- d) services furnished under certain payment rates (e.g., ASC payment rates, ESRD composite rates, or hospice rates);
- e) academic medical center services;
- f) implants in an ASC;
- g) EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility
- h) preventive screening tests, immunizations, and vaccines; and
- i) eyeglasses and contact lenses following cataract surgery.

- *Exceptions Related to Ownership or Investment Interests*

The following types of ownership or investment interests are excepted from the self-referral prohibition:

- a) publicly traded securities;
- b) mutual funds; and

- c) specific providers (certain rural providers, hospitals located in Puerto Rico, hospitals anywhere for designated health services provided by the hospital if the physician's ownership interest is in the entire hospital).
- *Exceptions Related to Compensation Arrangements*

The following types of compensation arrangements are excepted from the self-referral prohibition:

- a) Rental of office space;
- b) Rental of equipment;
- c) Bona fide employment relationships;
- d) Personal service arrangements;
- e) Physician recruitment;
- f) Isolated transactions;
- g) Arrangements with hospitals unrelated to the provision of designated health services;
- h) Group practice arrangements with a hospital;
- i) Payments by a physician for items and services;
- j) Discounts;
- k) Non-monetary compensation up to \$300;
- l) Fair market value compensation;
- m) Medical staff incidental benefits;
- n) Certain risk sharing arrangements;
- o) Compliance training; and
- p) Certain indirect compensation arrangements

## **PROCEDURE:**

### **I. RELATIONSHIPS WITH ACTUAL OR POTENTIAL REFERRERS AND THEIR FAMILY MEMBERS**

#### **A. General Prohibition on Paying, Offering, Soliciting, or Receiving Remuneration**

Employees must never provide or offer a bribe to induce the referral of federal health care program business by a person or entity to Giant Eagle Inc. Similarly, employees must never solicit or receive a bribe from any person or entity in exchange for referring

federal health care program business to that person or entity. Such activities are prohibited because they could result in violation of the Anti-kickback Statute and other health care fraud and abuse laws.

All financial dealings with actual or potential referrers or their family members must be appropriately documented and submitted to the Pharmacy Compliance Committee for approval. Any compensation paid by Giant Eagle Inc. to areferrer or a family member of a referrer must be based on the fair market value of services provided and may not be related to the volume or value of any business referred to Giant Eagle Inc.

#### **B. Interaction with Medicare Part D Plan Sponsors**

Ordinarily, neither Giant Eagle Inc. nor its employees may accept inducements in connection with the referral of potential enrollees to any Medicare Part D, Medicare Advantage (“MA”), or Medicare Advantage prescription drug (“MA-PD”) plan. All payments made by plans to Giant Eagle Inc. for its services will be fair market value, consistent with an arm’s length transaction, and for bona fide and necessary services, and will otherwise comply with all relevant laws and regulations, including the federal Anti-kickback Statute. Specifically, an employee cannot accept remuneration meant to induce or reward the employee to:

- switch federal health care program customers to different drugs,
- influence prescribers to prescribe different drugs, or
- steer patients to particular Medicare Part D plans.

#### **C. Discounts**

All discounts received from suppliers and vendors must comply with third party contracts and applicable laws and regulations. Giant Eagle Inc. will accept discounts from suppliers and vendors on items to be furnished to federal health care program beneficiaries only if the arrangement complies with the federal discounts safe harbor under the federal Anti-kickback Statute. Before discounts can be granted, the responsible party must submit the proposal to the General Counsel, who evaluates each proposal individually. Final proposal adoption must comply with Giant Eagle Inc.’s pricing approval guidelines.

#### **D. Professional Courtesy**

The offering of professional courtesy is a practice that government officials believe may constitute an illegal inducement. The term “professional courtesy” includes a number of different practices, such as: (1) the waiver of all or part of the fee for services provided to prescribing physicians or other referral sources, their families, or their employees, and (2) the waiver of coinsurance obligations or other out-of-pocket expenses for the same groups (often referred to as “insurance only” billing). If a professional courtesy is extended in a way that directly or indirectly takes into account the recipient’s ability to

affect past or future federal or state health care program referrals, the federal Anti-kickback Statute may be implicated. Consequently, Giant Eagle Inc. does not offer professional courtesy waivers or discounts to federal health care program beneficiaries or to actual or potential sources of federal health care program referrals, their families, or their employees.

## **II. RELATIONSHIPS WITH CUSTOMERS**

### **A. Reduction or Waiver of Copayments and Other Payment Responsibilities**

The federal Anti-Kickback Statute makes it illegal to offer, pay, solicit, or receive anything of value as an inducement to generate business payable by federal health care programs. In addition, federal law generally forbids offering or giving something of value to a federal health care program beneficiary if it likely will influence the beneficiary's choice of provider. Giant Eagle Inc. therefore does not reduce customer copayment obligations or payment responsibilities absent an individualized, good faith determination of financial need or a legal requirement, or where applicable rules otherwise permit.

### **B. Medicare Part D Promotional Activities**

Giant Eagle Inc. serves customers who are enrollees of various Part D plans. As such, employees may receive requests to educate potential enrollees on their plan choices or otherwise assist them with enrollment. When providing this assistance, employees are prohibited from steering enrollees to particular plans by offering them inducements or pressuring them in other ways. Giant Eagle Inc. requires all employees to follow certain guidelines established by the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that oversees administration of the Medicare prescription drug benefit.

Employees may assist a potential or actual enrollee with an objective assessment of his or her needs and plan options that may meet those needs. To this end, employees may engage in discussions with beneficiaries who seek information or advice regarding their options but should do so in strict compliance with Giant Eagle Inc.'s policies and procedures. When communicating with beneficiaries about plan options, employees cannot attempt to switch or steer them to a specific plan or group of plans to further the financial or other interests of Giant Eagle Inc.

To that end, employees cannot:

- accept enrollment applications or offer inducements to persuade beneficiaries to join particular plans;
- direct, urge, or attempt to persuade beneficiaries to enroll in a specific plan; or
- offer anything of value to induce plan enrollees to select Giant Eagle Inc. as its pharmacy.

Employees may distribute only those Medicare materials sanctioned by Giant Eagle Inc. Employees may inform prospective enrollees where they can obtain information on the full range of plan options. Possible sources of information include but are not limited to:

- the State Health Insurance Assistance Programs,
- plan marketing representatives,
- the State Medicaid Office,
- the local Social Security Administration Office,
- <http://www.medicare.gov/>, or
- 1-800-MEDICARE.

Plans or plan agents may conduct sales presentations and distribute and accept enrollment applications as long as the activity takes place in common areas, such as the space outside of where customers wait for services or interact with employees and obtain medications. If employees receive requests for such visits by plans, they should refer the requestor to the Pharmacy Compliance Officer.

In sum, when interacting with current or potential Part D plan enrollees, employees can:

- provide the names of plans in which Giant Eagle Inc. participates;
- provide information and assistance to beneficiaries in applying for low income subsidies;
- distribute Part D plan marketing materials in accordance with Giant Eagle Inc's policies;
- furnish objective information regarding specific plans, such as covered benefits, cost sharing, and utilization management tools;
- provide objective information on specific plan formularies, based on a particular customer's medications and health care needs;
- refer customers to other sources of objective information provided by third parties, such as state and federal agencies; and
- use marketing materials comparing plan information created by a non-benefit/service providing third-party.

When interacting with current or potential Part D plan enrollees, employees cannot:

- direct, urge, or attempt to persuade any prospective enrollee to enroll in a particular plan or to insure with a particular company based on Giant Eagle Inc's financial or other interests;
- collect enrollment applications;
- offer inducements to persuade beneficiaries to enroll in a particular plan;
- health screen when distributing information to patients because health screening is a prohibited marketing activity;
- offer anything of value to induce plan enrollees to select Giant Eagle Inc. as its provider;
- expect compensation in consideration for the enrollment of a beneficiary; or

- expect compensation directly or indirectly from the plan for beneficiary enrollment activities.

## **APPENDIX 5F**

### **RECORDS MANAGEMENT**

#### **PURPOSE:**

This policy aims to ensure that Giant Eagle Inc. retains records for appropriate periods of time; destroys records that are no longer useful; and establishes a systematic and efficient method for storing retained records.

#### **POLICY:**

Giant Eagle Inc's policy is to retain records in accordance with applicable statutes and regulations, its business needs, and its contracts.

#### **PROCEDURE:**

Giant Eagle Inc. has policies and procedures governing records management and has set forth mandatory procedures for storing, protecting, retrieving, and properly discarding records. Giant Eagle Inc. strives to comply with state and federal laws and regulations as well as accreditation agency standards regarding record retention. In determining retention periods, Giant Eagle Inc. also takes its business and compliance needs into account. Giant Eagle Inc. identifies the types of records it should retain and has established guidelines to determine if and when certain records may be discarded or must be retained. All employees are responsible for ensuring that accurate and complete documents are identified, retained, stored, protected, retrieved, and disposed of within their area of assigned responsibility in accordance with the policy.

Giant Eagle Inc. has a Storage of Pharmacy Documents policy that specifies which documents must be retained, the time of required retention, the proper storage and who is able to access the stored records. After the required storage time, the documents are destroyed in a HIPAA approved manner. The maintenance of the proper storage procedures is the responsibility of the pharmacy manager and is audited internally by Giant Eagle Inc. to assure compliance.